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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/730,878

12/09/2003

Ruchika Singhal

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28863 7590 08/03/2007  
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EXAMINER

KAHELIN, MICHAEL WILLIAM

ART UNIT

PAPER NUMBER

3762

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

ED

<b>Office Action Summary</b>	<b>Application No.</b> 10/730,878	<b>Applicant(s)</b> SINGHAL ET AL.	
	<b>Examiner</b> Michael Kahelin	<b>Art Unit</b> 3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 21 May 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Response to Amendment***

1. The amendment filed 6/8/2007 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The Examiner was unable to find any mention of hermetic housings in paragraphs [0062-0064] of application serial number 10/731,869.

Applicant is required to cancel the new matter in the reply to this Office Action.

### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 19 and 20 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The Examiner was unable to find support in the originally filed application for hermetic housings.

***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 1-13, 15-18 are rejected under 35 U.S.C. 102(e) as being anticipated by Berrang et al. (US 6,358,281, hereinafter "Berrang").

6. In regards to claims 1, 9 and 16, Berrang discloses an implantable device comprising at least two interconnected modules (Fig. 2, elements 2 and 3), each having a housing (col. 11, line 55); and an overmold encapsulating each of the housings (col. 12, lines 8-25) and comprising a lead connection module (Fig. 1, intersection of 6 and 16). Please note an alternate interpretation wherein electronic module (21) is housed by support disc (33) and battery (18) inherently comprises its own housing because the battery is a lithium ion or nickel metal hydride-type (col. 12, line 55). These batteries contain liquid electrolytes necessitating a housing. In this interpretation, the epoxy and gold act as the overmold. Further, regarding claim 16, the epoxy acts as a frame because it is rigid.

7. In regards to claim 2, at least one module contains electronic components (21).

8. In regards to claims 3 and 13, the overmold comprises a first material and a second material (col. 12, line 8) and the lead connection module is embedded within the

Art Unit: 3762

first material (because the lead conductors must pass through all coating materials (the epoxy, gold, palladium, titanium, and silicone of column 12, line 20) to reach the outside of the device, the lead connection module passes through the "first material").

Regardless of whether the lead is removably attached to the housing, the system comprises a lead connection module because the lead is connected to the internal electronics. This connection module comprises the conductors that connect 16 with the internal electronics 21. As the various housing and coating materials cover the conductors that connect the leads to the internal electronics (see Figure 2), these conductors are embedded, and a lead connection module.

9. In regards to claims 4, 10 and 17, the first material is non-elastomeric; depending on whether the epoxy resin, gold, or the other listed materials is considered to be "the first material".

10. In regards to claim 5, the device includes at least one feed-through wire (col. 11, line 3).

11. In regards to claims 6 and 7, the lead connection module necessarily includes a mechanical lead securing mechanism because the lead is attached to the device and is tool-less because it is integral.

12. In regards to claim 8, the maximum thickness is between 4 and 8 millimeters (col. 10, line 9).

13. In regards to claims 11, 12 and 18, the second material is silicone (col. 12, line 25).

Art Unit: 3762

14. In regards to claim 15, the modules are horizontally distributed and separately encapsulated by the overmold (Fig. 2).

15. In regards to claims 19 and 20, the housings are hermetically sealed by the overmold (col. 12, line 18).

***Claim Rejections - 35 USC § 103***

16. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

17. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

18. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Berrang. Berrang discloses the essential features of the claimed invention except for an isodiametric lead. It is well known in the art to provide implantable devices with isodiametric leads to allow the leads to be easily manufactured by extrusion processes

Art Unit: 3762

and implanted with tubular catheters. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Berrang's invention by providing an isodiametric lead to allow the lead to be easily manufactured by extrusion processes and implanted with a tubular catheter.

### ***Response to Arguments***

19. Applicant's arguments filed 5/21/2007 have been fully considered but they are not persuasive. Applicant argued that Berrang discloses a single housing comprising two sections, thusly not anticipating the limitation of each module comprising a respective housing. However, regardless of Berrang's terminology, the two sections of Berrang's disclosure can be interpreted as housings because they contain or support elements. There is nothing in the claim language that requires that the two housings not be comprised of the same integral material, because this integral material comprises two hollows, or housings. Further, the argument that the epoxy does not cover the edges of the ceramic substrate, thus does not "house" element 2 and 3 because the epoxy surfaces are merely components of elements 2 and 3; is not moving because the claim language does not require that the housing "houses" the modules, only that the modules comprise housings. Because each of elements 2 and 3 comprise the hollow housing areas defined by the elements cited above, Berrang meets the claim language. Further, neither "housing" in its common use, nor the remaining claim language requires that the element "housed" by the housing be totally surrounded on all surfaces. Lastly, claim 3 refers to "two thin housings".

Art Unit: 3762

20. Applicant's further arguments on page 9 of "Remarks" seem to be a misinterpretation of the grounds of rejection. The Examiner clearly indicated in the previous Office Action, and Applicant argued these grounds in the arguments addressed above, that the epoxy forms the housings which modules 2 and 3 require. Nowhere in the previously presented rejections is Berrang's gold layer considered to be the housing.

21. Applicant further argued that the alternative interpretation that Berrang's element 33 houses the electronics module and the inherently present housing for the liquid electrolyte battery (18) comprises the second module is improper because the support disc (33) in no way "houses" the electronics module (21). However, the Examiner maintains the interpretation and accompanying rejection based on the broad interpretation of the scope of "housing". Because element 33 is a protective element that contains or defines the negative space in which the electronics module resides, it is a housing.

22. In regards to the limitation of the embedded connection module, please see the explanation above.

23. In regards to the argument that Berrang is lacking a mechanical lead securing mechanism that is tool-less, the Examiner maintains the previous rejection on the grounds that the integral connection is mechanical and tool-less because it resists disconnection via mechanical forces (i.e. the mechanical strength of the comprising materials) and does not require a tool. Please note that nothing in the claim language requires the lead to be separable from the rest of the elements.



24. In regards to the argument that Berrang is lacking housings that are separately encapsulated by the overmold, please see the rejection of claims 1, 9, and 16, above. The Examiner has not indicated that the gold layer is the overmold, but the epoxy. Because this contains the housings, the housings are encapsulated and horizontally distributed (as in Figure 2).

### ***Conclusion***

25. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Kahelin whose telephone number is (571) 272-8688. The examiner can normally be reached on M-F, 9-5.

Art Unit: 3762

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MWK

*MWK*  
7/31/07

*George E. Evans*  
Primary

9/2/17